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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,780	08/30/2001	Kevin P. Baker	P2548P1C10	2570

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,780	BAKER ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. The request filed on 4/8/04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/943780 is acceptable and a RCE has been established. Claims 25-36 are pending and are currently under prosecution. An action on the RCE follows.

2. Claims 22-24 have been canceled.

Claims 25, 26, 35-36 have been amended.

3. Claims 25-36 are pending and under examination.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Response to Arguments

5. The rejection of claims 25-36 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility is maintained.

The response filed 4/8/04 has been carefully considured but is deemed not to be persuasive. The response states that the claimed polypeptides would be useful in creating degenerative oligonucleotide probes for isolation of genomic and cDNA

sequences that are amplified in lung and colon tumors and cites Lodish for support and use of the polypeptide sequence of PRO357 for creating oligonucleotide probes is a specific, substantial, and credible utility and it is undisputed that the nucleic acid (SEQ ID NO:68) encoding the polypeptide is amplified in lung and colon tumor (see page 6-9 of response). In response to this argument, while SEQ ID NO:68 is amplified in lung and colon tumors, the production of oligos from polypeptides that are 95-99% identical to SEQ ID NO:69 is not a specific, substantial, or credible utility because there is no indication that these polypeptides or SEQ ID NO:69 are overexpressed in tumors. The generation of probes would only lead to further research to identify the nucleic acids that would be possibly amplified in tumors. With regard to Lodish, this reference only shows producing probes and primers and sequencing DNA which is widely known in the art. The reference does not present evidence for a substantial utility. Degenerate oligonucleotides can be made to any polypeptide sequence and as such this utility is not substantial to the claimed nucleotides.

Thus, the claimed invention is not supported by either a substantial asserted utility or a well established utility.

6. The rejection of claims 22-36 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained.

The response filed 4/8/04 has been carefully considured and is deemed not to be persuasive. The response states that the claimed polypeptides have utility of generating degenerative oligos and site example 14 in the specification and Watson et al (see page 9-10 of response). In response to this argument, the remarks above address the rejection of 101 and as such one would not know how to use the claimed invention. The art of Watson teaches a method of obtaining a nucleic acid sequence and again this would be for research and using degenerate oligos to obtain a nucleic acid is for research purposes and generating oligos to any polypeptide is not substantial utility because it is not specific to the claimed polypeptides.

7. The rejection of claims 25-26, 33-34 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 4/8/04 has been carefully considured but is deemed not to be persuasive. The response states that one skill in the art after reading the specification would be able to find a polypeptide that is 95-99% identical to SEQ ID NO:69 and that is encoded by a nucleic acid that is amplified in lung or colon tumors and that nucleic acids that are 95-99% identical to SEQ ID NO:68 or SEQ ID NO:69 "might also be isolated from lung or colon cancer tissues" (see page 12 of response). In response to this argument, it seems clear that applicant is not in possession of the claimed invention

because the response admits that one "might also be isolated" which indicates they were not isolated at the time of the claimed invention.

The response further states that Examples 13 and 14 of the training materials are analogous to claims 25 and 26 and the claims describe distinguishing attributes that are shared by the genus (see pages 12-13 of response). In response to this argument, as stated previously Example 14 of the Guidelines is directed to an enzyme that has the sequence of SEQ ID NO:3 or is 95% identical to SEQ ID NO:3 and catalyzes the reaction of A to B. The instant claims are directed to polypeptides that are 95-99% identical to SEQ ID NO:69 wherein the nucleic acids are amplified in lung and colon tumors. While the claims require the amplification of the nucleic acid, this "function" is only the "function" of SEQ ID NO:68, the specification does not disclose any other polypeptides that are 95-99% that would be encoded by a nucleic acid be that is amplified in lung or colon tumors. The specification teaches that the method to "assay" for expression requires the nucleic acid of the PRO nucleic acid of SEQ ID NO:68 or an antibody to the protein of SEQ ID NO:69 (see page 69). The specification does not teach how one would or could find any other polypeptide that is 95-99% to SEQ ID NO:69 which is encoded by a nucleic acid that is amplified in lung or colon tumors or which regions or parts of the nucleic acid of SEQ ID NO:68 would be used to find such. The specification does not provide written description for the claimed polypeptides.

8. The rejection of claims 22-36 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 4/8/04 has been carefully considured but is deemed not to be persuasive. The response states that the determination is based on In re Wands and the response summarizes the factors and comments on their relationship to the claims. The first substantive argument is in "Level of predictability in the Art" on pages 15-17. The response states that even though Applicants do not specifically state which portions of the disclosed wild type sequence might be altered yet still lead to a functional polypeptide, obtaining such sequence variant is not unpredictable and the specification teaches mutagenesis and the PRO357 sequence possesses significant homology to the acid labile subunit of insulin-growth factor and therefore one would compare the claimed polypeptide sequence to the acid labile subunit and minimize amino acid changes in regions of high homology (see page 16 of response). In response to this argument, the acid labile subunit is not over expressed in lung or colon tumor and as such why would one look to this sequence. In addition, the response again does not address the unpredictability in the art as cited in the references in the rejection. Although one may be able to make a polypeptide that is 95-99% identical to SEQ ID NO:69, it would be unpredictable which sequence would encode a polypeptide that is amplified in lung or colon tumors. The response further states that the specification teaches SEQ ID NO:69 is encoded by a nucleic acid that is amplified in lung or colon tumors and Example 28 describes various assays to determine that SEQ ID NO:68 is amplified (see page 17 of response). In response to this argument, there is no disputing that SEQ ID NO:68 is

amplified in lung or colon tumor, again the only nucleic acid that is amplified is SEQ ID NO:68 which encodes SEQ ID NO:69. There is no other nucleic acid other than SEQ ID NO:68 that is shown to be amplified. In addition, it would be undue experimentation to determine the myriad of polypeptides that are 95-99% to SEQ ID NO:69 which are encoded by nucleic acids that are amplified in lung and colon tumors. The specification does not teach how to use such polypeptides or if the nucleic acid is amplified in tumor. The specification may describe obtaining SEQ ID NO:69 but the specification does not teach overexpression of SEQ ID NO:69 or how to determine which if any polypeptide that is 95-99% identity to SE QID NO:69 is encoded by a nucleic acid that is amplified in tumor cells. There is no evidence that the polypeptide of SEQ ID NO:69 or any polypeptide that is 95-99% to SEQ ID NO:69 is amplified in lung or colon tumor.

The response further states that the specification teaches an open reading frame and isolation of PRO357 from lung and colon tissue and again points to Example 28 and that the specification teaches how to determine 95-99% identity to a sequence and methods of assaying (see pages 18-19 of response). In response to this argument, while one can alter the amino acid sequence of the PRO357 protein, again the art sited by the examiner is evidence that alteration of a polypeptide sequence is unpredictable and this is even more true as the PRO357 protein does not has a function or activity in order to determine if alterations in the amino acid sequence can be tolerated.

The specification does not demonstrate that the polypeptide of SEQ ID NO69 is overexpressed and in addition the prior art cited in the rejection demonstrates the unpredictability in the art of protein expression as well as protein chemistry and

substitutions in protein sequences which was not addressed in the response except for the Fu reference in the previous response.

In view of the lack of guidance, lack of examples, and lack of predictability in the art as evidenced from the above references, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832

LARRY R. HELMS
PRIMARY EXAMINER

LARRY R. HELMS, PH.D
PRIMARY EXAMINER